IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicant	:	Leatherbury et al.	
Filed	:	02/23/2004	
TC/A.U.	:	3733	
Examiner	:	Kim, John	
For	:	BONE AND CARTILAGE IMPLANT DELIVERY DEVICE	
Docket No.	:	121-02	
Customer No.	:	23713	

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June 6, 2006	/bkroge/
Date	B. Kroge

AMENDMENT AND RESPONSE TO OFFICE ACTION

Commissioner for Patents
Arlington, VA 22313-1450

Sir:

In response to the Office Action mailed February 22, 2006, Applicants respectfully request entry of this Response and reconsideration of the rejections in light of Applicants' amendments and arguments. Please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 8 of this paper.

Amendments to the Claims:

The listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1. (currently amended) A bone or cartilage implant delivery device comprising:

   a tubular outer shaft having a proximal and distal end, a longitudinal axis, and an internal bore along the longitudinal axis of said outer shaft, wherein the distal end of said outer shaft is suitable for holding an implant; and

   an inner shaft having a distal end and a proximal end, wherein said proximal end of the inner shaft is suitable for insertion into a defect, said inner shaft adapted to fit within said internal bore of the outer shaft so that the inner shaft and the outer shaft are slidably engaged.

2. (original) The device of claim 1 wherein one or more of the shafts comprise means to provide friction-retarded movement of the inner shaft through the outer shaft.

3. (original) The device of claim 1 also comprising an implant disposed within the distal end of said outer shaft.

4. (withdrawn) The device of claim 1 wherein the inner shaft has a cannula through its center.

5. (original) The device of claim 3 also comprising at least one slot in the distal end of the outer shaft for visualizing said implant.

6. (withdrawn) The device of claim 1 wherein the distal end of the outer shaft comprises tapered leaves.

7. (withdrawn) The device of claim 1 further comprising a snap-bead groove disposed on the distal end of the outer shaft.

8. (original) The device of claim 1 further comprising smooth, rounded surfaces on the proximal and distal ends of the outer shaft and inner shaft.

9. (withdrawn) The device of claim 1 wherein a section of the inner surface of the outer shaft has serrated teeth frictionally enagable with serrated teeth on a corresponding section of the outer surface of the inner shaft.

10. (withdrawn) The device of claim 1 wherein a section of the inner surface of the outer shaft has beads disposed thereon and a corresponding section of the outer surface of the inner shaft has ridges disposed thereon so that when the inner shaft is moved distally or proximally through the outer shaft, the beads frictionally engage with the ridges.

11. (withdrawn) An implant cutting device for cutting off a protruding end of an implant disposed within the implant delivery device of claim 1, said cutting device comprising a base comprising a vertical hole therethrough for receiving said protruding end of said implant.

12. (withdrawn) The implant cutting device of claim 11 wherein said vertical hole adapted for receiving said protruding end of said implant has an upper diameter slightly larger than the outer diameter of said shaft and a lower diameter less than the outer diameter of said shaft.

13. (withdrawn) The implant cutting device of claim 11 also comprising means for receiving at least one cutting blade.

14. (withdrawn) The implant cutting device of claim 11 also comprising at least one cutting blade adapted to slide within said means for receiving at least one cutting blade and cut off the protruding end of said implant.

15. (withdrawn) The implant cutting device of claim 14 wherein said at least one cutting blade intersects said vertical hole at the point where said upper diameter meets said lower diameter.

16. (withdrawn) An implant capsule loader for inserting an implant into the outer shaft of the implant delivery device of claim 1, said capsule loader comprising:

a hollow tube having a front end and a back end with an opening therethrough, and adapted to fit within the distal end of said outer shaft.

17. (withdrawn) The capsule loader of claim 16 comprising a backplate disposed within said hollow tube covering the opening in the back end of said tube.

18. (withdrawn) The capsule loader of claim 16 also comprising at least one flexible leaflet along the outer surface of said hollow tube fixed at the front end of said hollow tube and having a free end toward the back end of said hollow tube, said flexible leaflet having an outwardly-extending prong at the free end thereof; said prong being adapted to fit within a hole in said outer shaft.

19. (withdrawn) The capsule loader of claim 18 comprising a plurality of flexible leaflets.

20. (withdrawn) The capsule loader of claim 16 comprising an implant disposed therein.

21. (withdrawn) An implant delivery system comprising:

an implant delivery device comprising a hollow outer shaft, and an inner shaft movably disposed therein; and an implant cutting device comprising means for receiving an implant protruding from said outer shaft and a cutting blade for cutting off said protruding portion.

22. (withdrawn) The implant delivery system of claim 21 also comprising an implant capsule loader comprising a hollow tube adapted to contain an implant and to fit within and be attached to an end of said hollow shaft.

23. (withdrawn) The implant delivery system of claim 22 also comprising an implant.

24. (currently amended) A method for delivering a bone or cartilage implant into a defect in a tissue having an unmeasured depth using ~~the~~ an implant delivery device comprising a tubular outer shaft having a proximal and distal end, a longitudinal axis, and an internal bore along the longitudinal axis of said outer shaft; an inner shaft having a distal end and a proximal end, wherein said proximal end of the inner shaft is suitable for insertion into a defect, said inner shaft adapted to fit within said internal bore of the outer shaft so that the inner shaft and the outer shaft are slidably engaged, said method ~~device of claim 1~~ comprising the steps:

inserting said implant into the distal end of said outer shaft ~~loading device~~, wherein when said implant is disposed in said outer shaft ~~loading device~~ the proximal end of the inner shaft protrudes from the proximal end of the outer shaft and the length of said implant and equals the length of the protruding section of the inner shaft;

inserting the proximal end of the inner shaft into the defect until the proximal end of the inner shaft contacts the bottom of the defect;

advancing the outer shaft in the proximal direction until the proximal end of the outer shaft contacts the surface of tissue surrounding the defect, causing a portion of the implant to extend beyond the distal end of the outer shaft;

cutting off the portion of the implant extending beyond the distal end of the outer shaft, leaving a remaining portion disposed within the outer shaft;

placing the distal end of the outer shaft ~~loading device~~ over the defect; and

distally advancing the inner shaft to push the portion of the implant remaining after cutting into the defect.

25. (original) The method of claim 24 further comprising placing a cap around the distal end of the outer shaft after the portion of the implant extending beyond the distal end of the outer shaft has been cut off and adding a bioactive fluid to the distal end of said outer shaft.

26. (currently amended) A kit comprising at least one bone or cartilage implant delivery device, said implant delivery device comprising:

a tubular outer shaft having a proximal and distal end, a longitudinal axis, and an internal bore along the longitudinal axis of said outer shaft, wherein the distal end of said outer shaft is suitable for holding an implant; and

an inner shaft having a distal end and a proximal end, wherein said proximal end of the inner shaft is suitable for insertion into a defect, said inner shaft adapted to fit within said internal bore of the outer shaft so that the inner shaft and the outer shaft are slidably engaged.

27. (original) The kit of claim 26 further comprising an implant.

28. (original) The kit of claim 26 further comprising a knife.

29. (original) The kit of claim 26 comprising a plurality of bone or cartilage implant delivery devices each having different sizes of internal bores and inner shafts.

REMARKS/ARGUMENTS

As a result of the reply filed January 17, 2006, claims 1-5, 8 and 24-29 are currently pending in this application. Claims 1, 24 and 26 are hereby amended to clearly recite that the distal end of the claimed delivery device is suitable for holding an implant while the proximal end of the inner shaft is suitable for insertion into a defect. Support for these amendments can be found on page 2, lines 26-30, page 3, lines 1-5, and page 10, line 30, through page 11, line 11, of the specification as filed. Claim 24 is further amended to delete the term "said loading device" and to be an independent claim instead of depending from claim 1. Claim 4 is hereby withdrawn as being drawn to a nonelected species.

In the Office Action mailed February 22, 2006, the Examiner rejected the claims on the grounds of nonstatutory obviousness-type double patenting over co-pending Application No. 11/292,807. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not yet been patented. "If the provisional double patenting rejection in one application is the only remaining rejection in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent." (MPEP §804 (I)(B)) Applicants believe the remaining rejections raised by the Examiner are cured by the present response and therefore request that the provisional double patenting rejection be withdrawn.

The Examiner objected to drawings under 37 CFR 1.83(a) for failing to show the cannulated inner shaft as claimed in claim 4. The cannulated inner shaft is depicted in figures 8A-8C and figures 10A-10C. However, Applicants elected the species of the delivery device as depicted in figures 1-3 in response to the election of species requirement. Accordingly, claim 4 is withdrawn as being drawn to a nonelected species. Since claim 4 is no longer pending in this application, it is believed the drawings are acceptable.

Claims 24 and 25 were rejected under 35 USC §112 because the limitation "said loading device" contained in claim 24 did not have antecedent basis. Claim 24 is hereby amended to delete the "said loading device" limitation and to be an independent claim. No other rejections were made against claims 24 and 25; therefore, it is believed claims 24 (as amended) and 25 are allowable.

The Examiner rejected claims 1, 2, 3, 5, 26, 27 and 29 under 35 USC 102(b) as being anticipated by Torrie et al. (U.S. 6,358,253). The Examiner asserted that Torrie et al. disclose a tubular outer shaft with proximal and distal ends, a longitudinal axis and an internal bore, and an inner shaft which slides inside the outer shaft. However, the delivery device of the present invention specifies that the distal end of the delivery device is able to hold an implant while the proximal end of the inner shaft (the end opposite to the implant) is suitable for insertion into a defect. "Suitable for insertion into a defect" is defined on page 3, lines 3-5, of the specification as an inner shaft having a size and shape allowing it to fit within a bone or cartilage defect without distorting or damaging the tissue layers. Independent claims 1 and 26 are hereby amended to clearly recite that the distal end of the claimed delivery device is suitable for holding an implant while the proximal end of the inner shaft is suitable for insertion into a defect.

Torrie et al. disclose a delivery device having an inner shaft, where one end of the device is able to hold an implant; however, Torrie et al. do not disclose that the inner shaft at the opposite end from the implant is suitable for insertion into a defect as recited by the amended claims. As described above, the amended claims comprise an inner shaft which can be inserted into a defect without distorting or damaging the tissue layers. The inner shaft depicted by Torrie et al. in figure 2d and figure 6 contains a drill bit explicitly used to cut the bone or cartilage tissue. Similarly, the dilator depicted by Torrie et al. in figure 2e is designed to be inserted into the defect to "enlarge the hole to accommodate the graft" (column 4, lines 24-26). Neither of the inner shafts depicted in figures 2d or 2e are designed to be inserted into a defect without distorting or damaging the tissue layers.

Furthermore, Torrie et al. show that the end of the inner shaft that could be inserted into the defect is not at the opposite end from the implant. The drill (figures 2d and 6) and dilator (figure 2e) do not hold an implant. After the drill is used to create the defect in the tissue layers and the dilator enlarges the defect, the graft is implanted using an insertion tool (depicted in figure 2f and figure 9). One end of the insertion tool houses the implant while the other end terminates in a handle (labeled as 70 in the figures). Torrie et al. disclose (figure 2f, figure 9 and column 6, lines 34-36) that the handle (70) of the insertion tool is enlarged to provide the surgeon a better grip. The end of the insertion tool opposite to the implant is clearly larger than the defect and cannot be inserted into the defect. In addition, the inner shaft at the other end of the insertion tool is also not capable of insertion into the defect. Torrie et al. disclose that the length of the inner shaft of the insertion tool equals the length of the outer shaft so that the inner shaft is flush with the rim of the outer shaft when the insertion tool is fully inserted in the outer shaft (column 6, lines 59-65). Thus, the inner shaft of the insertion tool is physically prevented from extending beyond the outer shaft and from being inserted into the defect. Torrie et al. disclose that the length of the inner shaft can be adjusted in order to account for the height of the implant; however, this adjustment makes the length of the inner shaft shorter and less able to extend beyond the end of the outer shaft and into the defect (column 6, line 66, through column 7, line 9).

Claims 1 and 26 as amended recite a delivery device comprising a tubular outer shaft with proximal and distal ends, a longitudinal axis and an internal bore, and an inner shaft which slides inside the outer shaft, where the distal end of the outer shaft is suitable for holding and implant and the proximal end of the inner shaft is suitable for insertion into a defect. Claims 2, 3, 5, 27 and 29 depend from claims 1 and 26 and incorporate these limitations. As set forth in MPEP § 2131, to anticipate a claim under 35 U.S.C. 102 the cited reference must teach each and every element as set forth in the claim (quoting Verdegaal Bros. v. Union Oil Co. of California, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). Because Torrie et al. do not disclose a delivery device where one end is suitable for holding an implant and the opposite end has an inner shaft suitable for insertion into a defect without damaging or distorting the tissue layer, each and every

limitation of the amended claims are not disclosed. In light of the above arguments, Applicants request that the rejection under 35 U.S.C. 102(b) be withdrawn.

The Examiner also rejected claims 4 (now withdrawn), 8 and 28 under 35 USC 103(a) as being obvious over Torrie et al. in combination with other references. As described above, Torrie et al. do not disclose a delivery device where one end holds the implant while the other end has an inner shaft suitable for insertion into a defect. Furthermore, there is no suggestion from Torrie et al., alone or in combination with the other references, to arrive at the presently claimed device. There is no suggestion that the inner shafts disclosed by Torrie et al. could even be adapted to be suitable for insertion into a defect without damaging or distorting the tissue layer. Accordingly, Applicants request that the rejection under 35 U.S.C. 103(a) be withdrawn.

Conclusion

In view of the foregoing, it is submitted that this case is in condition for allowance, and passage to issuance is respectfully requested. If there are further issues related to patentability, the courtesy of a telephone interview is requested, and the Examiner is invited to call to arrange a mutually convenient time.

A shortened statutory period for reply was not specified in the Office Action; therefore, it is believed that this submission does not require the payment of any fees. However, if this is incorrect, please charge Deposit Account No. 07-1969 any fees due.

Respectfully submitted,

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